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Docket No. UF-T278
Serial No. 09/608,200Remarks

Claims 39-62 were pending in the subject application. By this Amendment, claim 39 has been amended and claims 51-62 have been cancelled. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 39-50 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

The applicants wish to thank Examiner Patel for the courtesy of the examiner interview conducted with the undersigned on April 20, 2004. The remarks and amendments set forth herein are consistent with the substance of that interview and are believed to address the outstanding issues as discussed during the examiner interview.

The amendments to the claims set forth herein have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 39-62 have been rejected under 35 U.S.C. §102(b) as being anticipated by Biondi *et al.* (U.S. Patent No. 6,158,432). The applicants respectfully traverse this grounds of rejection because the Biondi *et al.* reference does not teach or suggest the applicants' unique method for ventilation monitoring and control. Specifically, Biondi *et al.* does not disclose a system that recommends, without clinician input, a ventilator control setting for a particular patient at that particular time based on the evaluation by an intelligence system of at least one output signal.

The Biondi *et al.* system requires the clinician to select specific ventilator control settings. The Biondi *et al.* system then monitors the performance of the system and, based on simulator algorithms, adjusts the mechanics of the system to effect the directions that were selected by the clinician. The Biondi *et al.* system does not, and cannot, recommend appropriate settings without clinician input to best facilitate patient care. Rather, the Biondi *et al.* system simply tries to carry out the operator's instructions. It is important to recognize that, when the current applicants refer to

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“ventilation control settings” they are referring to the settings that, when using the Biondi *et al.* system, must be entered by a clinician.

Please note the following passage in the Biondi *et al.* patent.

One feature of the ventilator control system 10 is that it can be configured to provide an assisted phase of a breath to the patient 20. As noted previously, the accumulated volume of gas inhaled by the patient as a result of his spontaneous respiratory muscle activity can be monitored. To accomplish this, the sensor monitoring system 19 measures the flow of gas inhaled by the patient 20 at the beginning of the inspiration phase of the breath and integrates the flow to provide the measured volume. The embedded controller 14 compares the measured volume to a trigger volume set by the clinician 16, and adjusts the plurality of controls within the pneumatic system 41 when the measured accumulated volume exceeds the trigger volume to provide an assisted phase of a breath. The embedded controller 14 also may adjust the trigger volume dynamically according to measured patient flow and pressure signals indicating the phase of the respiratory cycle. In particular, the embedded controller 14 may increase the trigger volume set by the clinician 16 during periods of the breath where increasing the pressure at the airway of the patient 20 may be induced by changes in the pneumatic system 41, and not by spontaneous efforts of the patient.

The applicants respectfully submit that the cited passage illustrates important distinctions between the applicants’ invention and the Biondi *et al.* system. Please note, for example, the reference to input provided by the clinician (fourth sentence). The simulator disclosed by Biondi *et al.* applies predetermined data structures with predetermined computational instructions to monitor patient ventilation (see for example, col. 13, line 57 through col. 14, line 62). This is in contrast of the current invention.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH*,

supra; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

The current applicants respectfully submit that Biondi *et al.* do not disclose the currently-claimed method wherein, without clinician input, an intelligence system evaluates output signals and ventilator parameter signals to recommend ventilator control settings. Because Biondi *et al.* do not disclose such a system, the applicants' claims cannot be said to be anticipated by Biondi *et al.*

The distinctions between the current invention and the Biondi *et al.* system are not trivial. In fact, it is precisely the differences between the current invention and Biondi *et al.* that make the current invention particularly advantageous. The Biondi *et al.* system only uses rigid algorithms to try to control the ventilator in order to effect settings entered by the operator. Thus, the care of the patient still depends entirely on judgments made by the operator. In contrast, the subject invention provides a system whereby a multiplicity of variables can be monitored in order to assess the need of a particular patient. These variables, which can include various measures of the patient's physiological response to the ventilator can then be used to achieve the appropriate therapeutic goal. By carefully monitoring the patient in this way, it is now possible to improve and expedite recovery. This is, of course, a tremendous benefit to the patient, the caregiver and the hospital. Such an advantageous method is neither disclosed nor suggested by Biondi *et al.* Accordingly, the applicants respectfully request reconsideration and withdrawal of the prior art rejection based on Biondi *et al.*

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

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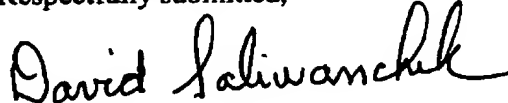
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The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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